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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,406	02/09/2004	David J. Burke	034008-003	6608

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BUCHANAN, INGERSOLL & ROONEY PC
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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
11/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com
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Office Action Summary	Application No.	Applicant(s)	
	10/773,406	BURKE ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15-17,23 and 27-45* is/are pending in the application.

4a) Of the above claim(s) *27,28,33-40 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,15-17,23,29-32,41 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/07 has been entered.

2. Claims 1-12, 15-17, 23, 29-32, 41 and 43 -45 are under consideration in the instant application.

3. Applicant's submission of IDS filed on 7/23/07 has been considered. However, foreign patent documents, '136 publication and the '501 publication are considered to the extent to the abstract as Applicant fails to provide the entire copy.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 6 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the office action mailed 3/9/07. This is a New Matter rejection.

Applicants' arguments filed on 9/10/07 have been fully considered but they were not persuasive.

Applicants traversed the rejection based on the support was provided throughout the specification because concentrations of 1.7mg/ml, 5mg/ml, 20mg/ml, and 50mg/ml were disclosed.

However, the specific range including the term "about" in the phrase " about 1.7 mg/ml to about 50 mg/ml" upon addition of the phrase "to about 50mg/ml" is not supported either by the specification or original claims.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-12, 15-17, 23, 29-32, 41 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6, 914,128 B1, of record, in view of Gordon et al. (Gastroenterology, 2001, 121:268-274, of record) for the reasons set forth in the office action mailed 3/9/07.

Applicants' arguments filed on 9/7/07 have been fully considered but they were not found persuasive.

Applicants traversed the rejection based on that the conditions and data disclosed by the'128 patent cannot be extrapolated to another monoclonal antibody because of the specificity and efficacy of the monoclonal antibody. Therefore, an ordinary skilled in art would not have an expectation of success with the formulation of the '128 patent.

Applicants further traversed the rejection based on that the substitution of an antibody formulation with other buffer because of antibodies differ with its specificity and highly relevant to their behavior and efficacy in a formulation.

However, as taught in the '128 patent, the referenced stabilizing formulation is suitable to enhance the shelf life or effectiveness of the antibody formulation for various molecular targets which are structurally unrelated (col. 72-76, in particular) including cell surface molecules designated CD's, cytokines, growth factors, receptors and its ligands as well as enzyme inhibitors. The '128 patent also allows the combination of target molecules (col. 77-78, in particular).

As cell surface molecules are considered integrin, and the referenced formulation is suitable for antibodies to other cell surface molecules, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute the antibody in the formulation taught by the '128 patent with the natalizumab antibody as taught by Gordon et al. Therefore, one of the ordinary skill in the art would have had an reasonable expectation of success. It is reminded that the obviousness rejection does not require absolute predictability but only the reasonable expectation of success. MPEP 2143.02.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the antibody formulation taught by the '128 patent can be used for enhancing shelf life and effectiveness of antibody formulation. As the formulation stabilizes any antibody, it is expected that the antibody formulation taught by the '128 patent would stabilize the natalizumab taught by Gordon et al. as well.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, the combination of the references remains obvious.

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
November 8, 2007

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